February 22, 2007

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Darrell Sleep
Application No. 10/522,074

Examiner: Gudibande, S.R.
Group Art Unit: 1654
Confirmation No. 7594

Filed July 23, 2003

Gene and Polypeptide Sequences

(Atty. Docket No. P30358 USA)

Filed Electronically by Barbara G. Makariou on February 22, 2007

Reply to Requirement for Restriction,
As Set Forth In the Action, dated January 22, 2007

Sir:

In response to the Requirement for Restriction, dated January 22, 2007, Applicants elect to prosecute the claims of Group I, that is, claims 1 to 11 and 20 to 25. Applicants confirm their right to file divisional applications that include the non-elected claims.

The Examiner also required Applicants to elect a single designated polypeptide for generic claims 1 to 11 and 20 to 25. Applicants elect hereby SEQ ID NO: 28.

Applicants traverse the Examiner's requirement for an election of the claims of Groups I and II.

The Examiner has asserted that Groups I and II lack unity invention under PCT Rule 13.2

because their shared inventive technical feature is not a contribution over the prior art. The Examiner further asserts that the technical feature of the claims is the peptide -X_1-X_2-X_3-X_4-X_5 and cites Ogata et al. as disclosing this technical feature.

Applicants submit that the technical feature of the claims is not only the peptide -X_1-X_2-X_3-X_4-X_5. The claims require this peptide to be part of a leader sequence which also comprises a secretion pre sequence. The claims also require a protein that is heterologous to the leader sequence. Applicants submit that the totality of the technical features of the claims is a contribution over the prior art. As the claims of Groups I and II both require these technical features, these groups do not lack unity of invention.

Applicants also respectfully submit it would not be a serious burden for the Examiner to perform a search and examination of Groups I and II. The claims of Group I are directed to a polypeptide comprising a leader sequence, the leader sequence comprising (a) a secretion pre sequence, and (b) the following motif: -X_1-X_2-X_3-X_4-X_5. A "pre" or "signal" sequence is described in paragraph 0002 of the application as follows:

> Numerous natural or artificial polypeptide signal sequences (also called secretion pre regions) have been used or developed for secreting desired peptides, polypeptides and proteins (these terms are used interchangeably from hereon in) from host cells. The signal sequence directs the nascent protein towards the machinery of the cell that exports proteins from the cell into the surrounding medium or, in some cases, into the periplasmic space. The signal sequence is usually, although not necessarily, located at the N-terminus of the primary translation product and is generally, although not necessarily, cleaved off the desired protein during the secretion process, to yield the "mature" protein.

The claims of Group II are directed to a polypeptide comprising a leader sequence, the leader sequence comprising (a) a secretion pre sequence, (b) the following motif: -X_1-X_2-X_3-X_4-X_5, and (c) a secretion pro sequence. A "pro" sequence is described in paragraph 0003 of the application as follows:

> In the case of some desired proteins the entity that is initially secreted, after the removal of the signal sequence, includes additional amino acids at its N-terminus called a "pro" sequence, the intermediate entity being called a "pro-protein". These pro sequences may assist the final protein to fold and become functional, and are usually then cleaved off. In other instances, the pro region simply provides a cleavage site for an enzyme to cleave off the pre-pro region and is not

known to have another function.

Accordingly, each of Groups I and II is related to leader sequences comprising amino acid sequences related to secretion and/or folding of a polypeptide. Furthermore, the claims of Group II depend from claim 1 of Group I, indicating that upon the allowance of claim I, the claims of Group II would necessarily be allowable. In view of this relationship, Applicants assert that the Examiner has no added burden to examine Group II claims at the same time as the Group I claims.

A favorable action on the merits is requested respectfully.

Respectfully submitted,

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